



NDA 21-433S/-011

GlaxoSmithKline  
P. O. Box 13398  
Five Moore Drive  
Research Triangle Park, NC 27709-3398

Attention: Dawn Watson  
Director, Regulatory Affairs

Dear Ms. Watson:

Please refer to your supplemental new drug application dated November 21, 2007, received November 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent HFA (fluticasone propionate HFA) Inhalation Aerosol.

We acknowledge receipt of your submissions dated May 2, 7, and 12, and June 12, and 23, 2008.

This supplemental application provides for revisions to the labeling to provide additional pediatric safety information.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert, Information for the Patient) and submitted on June 23, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-433-S-011**".

### **PROMOTIONAL MATERIALS**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division of Pulmonary and Allergy Products and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ladan Jafari, Regulatory Project Manager, at (301) 796-1231.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D.  
Director  
Division of Pulmonary and Allergy Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Badrul Chowdhury  
7/1/2008 10:38:13 AM